

SEP 12 2006

**Exhibit 1**

**510(k) Summary  
Pride Mobility Products Corporation  
Go Go Mini Power Wheelchair**

K062160

**Submitter's Name & Address:**

Pride Mobility Products Corporation  
182 Susquehanna Avenue  
Exeter, Pa. 18643  
Phone: (570) 655-5574  
Facsimile: (570) 655-2990

**Contact Person:**

Thomas Schappert  
Official Correspondent

**Date Prepared:**

07-10-06

**Name of Device and Proprietary Name:**

Go Go Mini / Pride Mobility

**Common or Usual Name:**

3-Wheel Power Scooter

**Classification Name:**

Physical Medicine / Motorized Three-Wheeled Vehicle

**Product Code:**

INI

**Comparison to Predicate Devices:**

The Go Go Mini is equivalent to the Pride Mobility Sunrunner TE-777 (K923193) when comparing components, performance, maneuverability, stability, and structure. The performance characteristics and the position of the electronics and drive mechanisms are similar to achieve the same intended use function that enables the user to maintain optimum stability without hindering performance. The differences between the Sunrunner TE-977 (K923193) and the Go Go Mini is in the overall size, framework, and Control Mechanisms.

**Device Description:**

The Go Go Mini is a compact battery-operated three-wheel scooter having a programmable 45-amp "S" Drive Controller. Features include a removable molded plastic seat, a foldable tiller, and an off board charger. Additional safety features include electronic regenerative disc brakes, and rear anti-tip wheels. The Go Go Mini is designed for, but not limited to Pride Mobility Products Corp. providers / retailers and their consumers.

The Go Go Mini is designed with ultimate safety, stability, performance, and portability in mind. The main feature of the Go Go Mini is that it can be disassembled into 4 parts: the rear section, the front section, the battery pack, and the seat. This allows for ease of use when traveling or storing the unit.

**Intended Use:**

The intended use of the Pride Mobility Products Corp. Go Go Mini 3-Wheel Scooter, is to provide mobility to persons having limited walking capability, or simply to those who wish to ride a scooter for transportation purposes. .

**Non-Clinical Testing:**

Compliance to applicable Testing Standards is as follows:

ANSI/RESNA WC/01 Determination of Static Stability

ANSI/RESNA WC/02 Determination of Dynamic Stability

ANSI/RESNA WC/03 Effectiveness of Brakes

ANSI/RESNA WC/05 Overall Dimensions, Mass & Turning Space

ANSI/RESNA WC/08 Test methods for Static, Impact and Fatigue Strengths

ANSI/RESNA WC/09 Climatic Tests

ANSI/RESNA WC/10 Obstacle Climbing

ANSI/RESNA WC/15 Documentation and Labeling

ANSI/RESNA WC Vol. 2-1998 Section 21 – Requirements and Test Methods for Electromagnetic Compatibility.

ANSI/RESNA WC/93 Maximum overall Dimensions

CAL 117 – Flammability Testing

**Discussion of Clinical Testing Performed:**

N/A

**Conclusions:**

The Go Go Mini has the same intended use and similar technological characteristics as the Sunrunner TE-977 (K923193), moreover, the non-clinical testing and the predicate comparisons demonstrate that any differences in their technological characteristics do not raise any new questions of safety or effectiveness. Thus, the Go Go Mini is substantially equivalent to the predicate device, has passed all the necessary testing procedures, and is considered to be safe for user operation.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

SEP 12 2006

Mr. Thomas Schappert  
Official Correspondent  
Pride Mobility Products Corporation  
182 Susquehanna Avenue  
Exeter, Pennsylvania 18643

Re: K062160  
Trade/Device Name: Go Go Mini / Model SC30  
Regulation Number: 21 CFR 890.3800  
Regulation Name: Motorized three-wheeled vehicle  
Regulatory Class: Class II  
Product Code: INI  
Dated: August 25, 2006  
Received: August 29, 2006

Dear Mr. Schappert:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

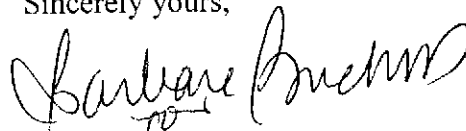
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Page 2 – Mr. Thomas Schappert

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120 . Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in dark ink, appearing to read "Mark N. Melkerson", written over a horizontal line.

Mark N. Melkerson  
Director  
Division of General, Restorative  
and Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K062160

Device Name: Go Go Mini / Three wheel Power Scooter

Indications for Use:

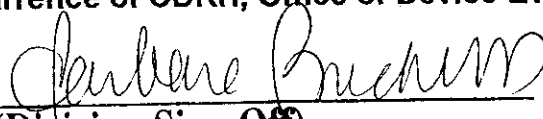
The intended use of the Pride Mobility Products Corporation Go Go Mini three wheel scooter, is to provide mobility to persons having limited walking capabilities, or simply to those who wish to ride a scooter for transportation purposes.

Prescription Use  X  AND / OR Over-The-Counter Use  X   
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

  
(Division Sign-Off)

Division of General, Restorative,  
and Neurological Devices

Page 1 of 1

510(k) Number K062160